GUIDELINE FOR CONVENED BOARD REVIEW OF RESEARCH

The Office for Human Subject Protection (OHSP) Policy 501 describes the levels of RSRB review for proposed research activities, including the type of research that will undergo convened board review procedures according to the regulations. This guideline describes the requirements, institutional standards, and procedures for the convened board review process by the RSRB.

1. Investigator Submission Requirements

a. The submitting Investigator must meet the qualifications and requirements of Principal Investigator (PI) as defined in *Policy 901 Investigator Responsibilities*.

b. When submitting applications for initial, continuing or modification review, Investigators must include all applicable materials for submission listed in OHSP *Policy 502 Types of RSRB Submissions*.
   - The applicable Protocol Template and Consent Form Templates may be utilized to ensure regulatory and institutional standards are met.

c. Upon receipt of an application by the RSRB, the RSRB Specialist completes a pre-review of the submission (e.g., to verify whether the submission materials are completed, required education is completed, protocol and consent form contain all necessary information, consent forms are consistent with the protocol, etc.). The Specialist may request more information from the Investigator during this pre-review process for clarification or completeness of the application. In addition, the Specialist may ask the Board Chair or Vice Chair to review or to provide input on the application in advance of the convened meeting. Once the application is considered complete for purposes of convened board review, the study will be assigned to a board meeting. If appropriate, the study may be re-assigned for consideration of expedited review (see OHSP *Guideline for Expedited Review of Research*).

2. Board Reviewer Assignments

a. The RSRB Specialist assigns the protocol to a board member with the appropriate expertise (which may include the Board Chair or Vice Chair). The following will be considered when making this assignment and the Specialist may consult with the RSRB Chair or Vice Chair, as needed:
   - Reviewer's workload (i.e., other study assignments).
   - Potential conflicts of interest (OHSP *Policy 902 Investigator Conflict of Interest*).
   - Need for special representation (e.g., vulnerable populations such as children or prisoners).

b. The RSRB primary reviewer is notified by the IRB online review system that a study has been assigned.

c. If it is determined at any point during the review process that supplemental review by a consultant is necessary, the process outlined in OHSP *Policy 402 RSRB Meetings* for "Selection of Consultants" will be followed.

3. Convened Board Review Procedures

a. Initial and Continuing Review

i. The assigned RSRB primary reviewer and RSRB members will conduct an in-depth review of submitted materials according to OHSP *Policy 402 RSRB Meetings*. In addition, for continuing review, all previous reviews and RSRB approved materials are available to the reviewer and board members.

ii. During the continuing review of research, the convened board will assess, as applicable, subject enrollment, study personnel, reports of new information, consent and documentation of consent, research results, previously approved modifications, data and safety monitoring reports, publications and any other items relevant to the level of research risk and ongoing conduct of the research to determine the following:

- The current consent document is accurate and complete;
- Whether significant new findings that might relate to the subject's willingness to continue participation in the research need to be provided to the subject;
- Whether verification from sources other than the Investigator is needed to ensure that no material changes have occurred since prior RSRB review.
- Whether all elements of the criteria for approval, per OHSP *Policy 404 Criteria for RSRB Approval of Research*, are still applicable as initially determined by the convened board.

b. Modifications to Previously Approved Research

i. Examples of modifications requiring review by the convened board include:

- Expansion of the eligibility criteria to a study involving greater than minimal risk;
- Increasing the total enrollment goal (locally) to a study involving greater than minimal risk;
- Alterations in the dosage or route of administration;
- Discovery of additional toxicities prompting revision to the consent form;
- Changes which, in the opinion of the RSRB Chair or designee, should be referred to the convened board.

ii. The RSRB primary reviewer and RSRB members will conduct an in-depth review of the modification and revised materials according to OHSP *Policy 402 RSRB Meetings*. All previous reviews and RSRB approved materials are available to all RSRB members for review.

iii. The convened board will review and discuss the submitted information and determine the following:

- Whether the modification affects one or more criterion for approval, as described in OHSP *Policy 404 Criteria for RSRB Approval of Research*;
- Whether the modification increases the risk to subjects who participate;
- Whether significant new findings that might relate to the subject's willingness to continue participation in the research need to be provided to the subject (i.e., re-consent of subjects previously enrolled and continuing research activities or interventions) and the method for such notification (e.g., consent revision, consent addendum, or new consent form).

4. Convened Board Review Determinations and Notifications

a. Once a review determination is made, the board's decision will be recorded in the online review system and in the meeting minutes. The possible RSRB voting motions that can be taken include: approved, approved with modifications to secure approval, defer, disapprove, or suspend (or termination for an active study), as outlined in OHSP *Policy 402 RSRB Meetings*.
   - When modifications are requested, the Investigator may respond to the requested changes or provide justification for not doing so. Responses will be reviewed by the RSRB Specialist, and the reviewer, as necessary, to makes a determination whether or not the Investigator addressed all modifications required by the board. If all modifications are addressed, documents are finalized and the study is submitted for approval. If not all modifications are addressed, or the Investigator's response includes considerable revisions beyond the scope of the convened board's requested modifications, the application and Investigator's response will be reviewed according to OHSP *Policy 402 RSRB Meetings*.
   - At the time of initial review, the RSRB reviewer may approve some components of the research study and allow an Investigator to initiate research activities only related to those approved components, and defer action on other components (see *OHRP Guidance on IRB Approval of Research with Conditions*).

b. Once the initial, continuing, or modification review is approved as described in OHSP *Policy 404 Criteria for RSRB Approval of Research*, the RSRB Specialist documents the convened board's decision, votes, and the approval period for initial and continuing reviews in the online review system. The Chair or Vice Chair will also complete the applicable RSRB checklist in the online review system to document any other required regulatory findings. Additional comments regarding the review determination may be included in the checklist, as applicable, including an explanation for any protocol requiring review more often than annually.

c. Determination of approval periods will be made as follows, with the expiration date being the last date the research activities may be conducted.

   i. For initial review, the approval period start and end dates are determined as indicated below:
      - Initial Review Approval Date = Date of the convened board meeting at which the study was approved or approved with modifications.

- Initial Review Effective Date = Date the Specialist, and Chair or Vice Chair as needed, confirms the modifications required by the convened board were satisfied.
- Initial Review Expiration Date = One year from Approval Date, minus one day (e.g., meeting date 04/10/2018 means expiration date is 04/09/2018).

ii. For continuing review, the approval period may not be greater than 364 days, and is determined as follows:
- Re-approval Date = Date of the convened board meeting at which the study was re-approved or re-approved with modifications.
- Re-approval Effective Date = Date the Specialist, and Chair or Vice Chair as needed, confirms the modifications required by the convened board were satisfied.
- Re-approval Expiration Date = One year minus one day Re-approval Date (e.g., board meeting date at which study was re-approved with modifications required to secure approval is 04/09/2018; therefore, re-approval expiration date is 04/08/2019).

iii. Determining approval periods when a study is Approved with an Approval Period of Less Than 1 Year:
- If the convened board approves a study for less than 1 year, e.g., 6 months, the expiration date will be 6 months from the Approval Date. For a study approved by the convened board on 10/05/18, the expiration date will be 04/04/19.

d. Investigators are notified of convened board review actions according to OHSP *Policy 403 Notification of RSRB Determinations*.

e. The Institutional Official (IO), or as delegated to the OHSP Director, has access to all research that is approved by convened board review in the online review system.
- If research requires further action or review by the UR as determined by the IO (or designee), the requirements will be communicated to the Director of the RSRB and RSRB Chair.